## **REMARKS/ARGUMENTS**

Applicants have received and carefully reviewed the Final Office Action mailed August 16, 2010. Claims 1, 27, 29-33, 40-49, 61, and 62 are currently being reviewed, with claims 29-33 previously withdrawn from consideration. Claims 1, 27, 40-49, 61, and 62 have been rejected. Applicants respectfully traverse all adverse assertions and rejections presented in the Office Action. With this amendment, claim 43 has been canceled and claim 44 has been amended to correct a typographical error. No new material has been added. No substantive claim amendments are presented herein, and Applicants submit that the amendments present no new search burden. Therefore, entrance and favorable consideration of the above amendments and the following remarks are respectfully requested.

## Claim Rejections - 35 USC § 112

Claims 43-45 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that the claims appear to combine embodiments that were not originally intended to be combined. Applicants respectfully traverse this rejection.

Without conceding the correctness of the rejection, and in the interest of advancing prosecution, claim 43 has been canceled. Applicants submit that the subject matter of claims 44 and 45, which as amended now properly depend from claim 42, would be recognized as being described in the pending specification by one of ordinary skill in the art. For example, gelatin capsule 98 could be considered as the connector disposed between the flexible disk 70 and the hemostatic body 90 of the pending claims, with element 92 serving as the claimed resilient extension member, as described in paragraph [0036] and shown in Figure 6C.

Accordingly, Applicants submit that claims 44 and 45 properly satisfy the written description requirement of 35 U.S.C. §112, first paragraph, and withdrawal of the rejection is respectfully requested.

## Claim Rejections – 35 USC § 103

Claims 1, 27, 40-46, and 61-62 were rejected under 35 U.S.C. §103(a) as being

unpatentable over Nash et al. (U.S. Patent No. 5,700,277) in view of Hannam et al. (U.S. Patent No. 5,649,959). After careful review, Applicants must respectfully traverse the rejection.

With respect to independent claim 1, the Final Office Action asserts that Nash et al. disclose a release mechanism "positioning and releasing the flexible plug intravascularly". Applicants respectfully disagree. Applicants previously noted that Nash et al. do not appear to disclose the asserted capability. Instead, Nash et al. expressly teach away from releasing the flexible plug intravascularly at column 6, lines 26-28, where Nash et al. state: "[i]n order to ensure that no portion of the anchor member can break off and separate from the closure 20 when the anchor member 32 is deployed within the blood vessel..." Thus, plug member 30 does not appear to release anchor member 32 instravascularly, as claimed.

In the Response to Arguments of the Final Office Action, the Examiner asserts that "[t]he release member as discussed below positions the plug intravascularly and releases it from the sheath" (emphasis added). Applicants note that releasing the plug from the sheath is not claimed, nor does a sheath appear in the pending claim. Additionally, Applicants note that the asserted release mechanism (plug member 30) does not in fact "release[s] it from the sheath" as asserted by the Examiner. Nash et al. appear to describe the operation of the device at column 7, line 28 through column 8, line 55. In particular, Applicants respectfully direct the Examiner's attention to the following passages: column 7, lines 46-50; and column 8, lines 7-10, 16-19, and 28-33. Nash et al. do not appear to disclose that plug member 30 releases anchor member 32, as asserted by the Examiner. Instead, filament 34 appears to pull plug member 30 out of instrument 10 as instrument 10 is retracted. During retraction of instrument 10, filament 34 remains under tension, connecting anchor member 32 to instrument 10 to effect radial deformation of plug 30 under axial compression. Thus, plug member 30 does not appear to release anchor member 32 from the sheath, as asserted by the Examiner. Applicants submit that the only action that appears to "release" anchor member 32 from the sheath is the cutting of filament 34, which does not read on the pending claim.

Furthermore, the Examiner asserts that "the suture can be considered "not directly attached to the flexible plug" since the plug can be considered element 32 excluding the

portion 52 that engages the suture since the ends and bottom of the element 32 anchor the apparatus to the subject (Fig 9) while portion 52 engages the suture (Fig 19)". Applicants respectfully disagree.

Nash et al. expressly describe element 52 as a "hemispherical dome-like projection 52 is located at the center of the top surface" (emphasis added), and also expressly state that "anchor member 32 has a generally planar top surface 46". See column 5, lines 60-67. Column 6, lines 5-9 expressly describe a passageway 56 "extends transversely across the member 32 below the projection 52 and close to the bottom surface 48" (emphasis added) and that "filament 34 is threaded through the passageway 56". Accordingly, Nash et al. appear to expressly disclose filament 34 is directly attached to anchor member 32 via passageway 56, in contrast to the pending claim. Figures 2, 3, 5, 6, 8, and 9 clearly show that filament 34 passes through passageway 56 within the interior of anchor member 32, below the top surface 46 of anchor member 32, and below dome-like projection 52. While Figure 19 does appear to show that filament 34 may at least partially wrap around projection 52, filament 34 passes through passageway 56 at the center of anchor member 32. This is further illustrated by flexible strip 60 (shown in Figure 19 below projection 52 and above passageway 56) which is expressly disclosed as being within anchor member 32. See column 6, lines 30-34.

Accordingly, Nash et al. do not appear to teach at least these claim limitations. Hannam et al. do not appear to remedy the shortcomings of Nash et al. in this respect.

Turning to independent claim 40, the Final Office Action asserts that Nash et al. disclose a connector 78 is disposed between the disk and the hemostatic body. As previously discussed, while Nash et al. do appear to disclose a spacer member 78 disposed between the flexible disk and the hemostatic body, spacer member 78 does not appear to couple the two elements. Instead, spacer member 78 appears to be just that – a slidable spacer that can be disposed between and spaced apart from the flexible disk and the hemostatic body. As clearly visible in Figures 4-9 and 19, spacer member 78 does not appear to couple the flexible disk to the hemostatic body.

In the Response to Arguments of the Final Office Action, the Examiner asserts that the "term "couple" is a very broad term and element 78 extends between the two

elements". Applicants submit that regardless of the asserted broadness of the claim term "couple", MPEP 2111.01 provides the following guidance: "It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. Ferguson Beauregard/Logic Controls v. Mega Systems, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003)" and "[w]here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings."

Applicants submit that the definition applied by the Examiner is outside of the "ordinary" and "customary" meaning of the term. One of ordinary skill in the art would not consider an element (spacer 78) that merely lies between two other elements (anchor member 32 and plug member 30) to "couple" those two elements. Thus the Examiner's assertion that "element 78 extends between the two elements" reads on the claim term "coupling" appears to be improper. Accordingly, Nash et al. do not appear to disclose or suggest a connector disposed between the flexible disk and the hemostatic body, the connector coupling the flexible disk to the hemostatic body, as in claim 40.

For at least the reasons discussed above, Nash et al. do not appear to properly disclose or suggest all of the limitations of independent claims 1 and 40, as is required to establish a *prima facie* case of obviousness. Hannam et al. do not appear to remedy the shortcomings of Nash et al. with respect to claims 1 and 40. Therefore claims 1 and 40 are believed to be patentable over the cited references. Since claims 27, 41-46, 61, and 62 depend from claims 1 and 40 and add additional elements thereto, these claims are also believed to be patentable over the cited references. Applicants respectfully request that the rejection be withdrawn.

Claims 46-49 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,700,277) in view of Hannam et al. (U.S. Patent No. 5,649,959), and further in view of Kensey et al. (U.S. Patent No. 5,441,517). After careful review, Applicants must respectfully traverse the rejection.

For at least the reasons discussed above, Nash et al. in view of Hannam et al. do not appear to properly disclose or suggest all of the limitations of independent claim 40,

as is required to establish a *prima facie* case of obviousness. Kensey et al. do not appear to remedy the shortcomings of Nash et al. and Hannam et al. with respect to claim 40. Accordingly, claims 46-49, which depend therefrom and add additional elements thereto, are also believed to be patentable over the cited references. Applicants respectfully request that the rejection be withdrawn.

## Conclusion

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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